

## **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 59, 60, 64, 72-74, 76-79, 85, 88-95, 97, 100 and 101 are in the case.

### **I. THE INTERVIEW**

At the outset, the undersigned wishes to thank the Examiner (Mr. Saidha) and his supervisor (Mr. Nashed) for kindly agreeing to conduct an interview in this case. The interview was conducted on May 14, 2009 and was attended by Mr. Anton Gibson, a representative of the applicant, as well as by the undersigned. The courtesies extended by the Examiner and his supervisor were most appreciated. The substance of the interview will be clear from the comments presented below.

### **II. THE NEW MATTER REJECTION**

Claims 59, 60, 64, 72-74, 76-79, 85, 88-95, 97, 100 and 101 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement and as constituting the introduction of new subject matter. The Action alleges on page 3 that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, and that the subject matter contained in claims 59, 60, 64, 72-74, 76-79 85, 88-95, 97, 100 and 101 constitutes new subject matter not supported by the original disclosure. This rejection is respectfully traversed.

As discussed during the interview, and in particular as pointed out by Mr. Gibson, adequate written description support appears for the subject matter of the claimed invention in the specification as originally filed. In particular, it was noted that there are three examples of fusion proteins as disclosed in the specification, and that support is given in the specification for use in claim 59 of a polymer synthase selected from a microorganism of the genera listed in claim 59.

The first example appears in Example 6.1 (see, in particular, paragraphs [0104] and [0105]) which discloses a polymer synthase (PhaC1 from *P. aeruginosa*) fused with two N-terminally inserted cysteine residues (see also references to SEQ ID NO: 7 and 8 in paragraph [0105]).

The second example appears in Example 6.2.1 (see paragraphs [0107] to [0109]) which discloses a polymer synthase (PhaC1 from *P. aeruginosa*) fused with the FLAG epitope (amino acids DYKDDDDK). The FLAG-polymer synthase fusion protein is prepared using the primers: 5'-tatg**actagtgattataa**gatgatgataaaca-3' and 5'-tatg**tttatcatcatcatcttataat****actag**tca-3' (SEQ ID Nos. 10 and 11, SpeI restriction site in bold, FLAG epitope underlined). As disclosed in paragraph [0108], a polymer particle with two FLAG epitopes fused directly to the N-terminus of the polymer synthase phaC1 enabled binding of commercial anti-FLAG monoclonal antibodies.

The third example also appears in Example 6.2.1 (see paragraph [0113]) which discloses a polymer synthase (PhaC1 from *P. aeruginosa*) fused with the beta-galactosidase enzyme from *E. coli*. Amplification of the lacZ gene encoding beta-galactosidase from *E. coli* is carried out by means of PCR with primers which contain an SpeI restriction site: 5'-gg**actag**tatgaccatgattacggattcactggc-3' (SEQ ID No. 13, SpeI

restriction site in bold) and 5'-ccactagtttttgacaccagaccaactggtaatggtagcg-3' (SEQ ID No. 14, SpeI restriction site in bold) and the amplified gene (SEQ ID No. 15) is used to produce a beta-galactosidase-polymer synthase fusion protein. As disclosed in paragraph [0113], the beta-galactosidase-polymer synthase fusion protein is able to form polymer particles having beta-galactosidase activity.

Support for use of a polymer synthase from a microorganism of the genera *Ralstonia*, *Alcaligenes* and *Pseudomonas* appears in the specification at paragraph [0033]. Support for the species *R. eutropha*, *P. oleovorans*, *P. putida* and *P. aeruginosa* appears in the specification at paragraph [0035]. Support for *Aeromonas* and *Thiocapsa* appears in paragraph [0084] (Example 2) which makes the specific reference to two species, namely *Aeromonas punctata* and *Thiocapsa pfennigii*, as well as to *R. eutropha* and *P. aeruginosa*.

Based on the above, it is clear that full and adequate support appears in the specification as originally filed for the claimed subject matter. Agreement to this effect was reached during the interview. Withdrawal of the outstanding new matter rejection is accordingly respectfully requested.

### III. THE WRITTEN DESCRIPTION REJECTION

Based on the above discussion, it is believed clear that the specification provides adequate written description support for the claimed invention. Agreement was reached that the written description rejection would also be withdrawn. Such action is respectfully requested.

**IV. THE ENABLEMENT REJECTION**

Claims 59, 60, 64, 72-74, 76-79, 85, 88-95, 97, 100 and 101 stand rejected under 35 U.S.C. §112, first paragraph, on the ground that the specification while enabling for a process for producing polyhydroxy carboxylate particles having surface-bound proteins, allegedly does not provide enablement for a process as presently claimed. This rejection is respectfully traversed.

As discussed during the interview, agreement was reached that the specification does provide adequate enablement for one of ordinary skill to carry out the claimed invention without the exercise of undue experimentation. Adequate exemplification is provided for carrying out the invention, in particular, in Example 6 as discussed above. Agreement was reached however that the claims would be amended to delete "abzyme". These amendments have been effected without prejudice to pursuing deleted subject matter in a separate continuing case. Reconsideration and withdrawal of the outstanding enablement rejection are accordingly respectfully requested.

**V. THE 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION**

Claims 89 and 90 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite in view of the reference to "biologically active" protein. In response, claims 89 and 90 have been amended to remove the term "biologically active". Other claims have also been amended to remove this terminology for consistency. Withdrawal of the rejection is respectfully requested.

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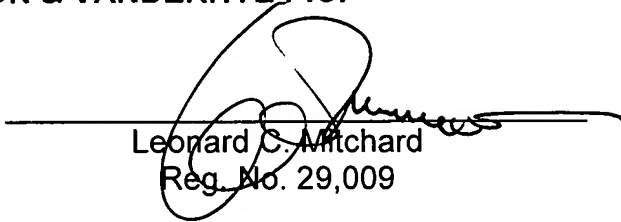
In light of the above, it is believed that with the arguments and amendments presented herewith, it is believed that the present application is in condition for allowance, early notice to that effect is respectfully requested.

Favorable action is awaited.

Respectfully submitted,

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